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Re-evaluation Note REV2017-07

Re-evaluation Project Plan for Tebufenozide

(publié aussi en français)

15 March 2017

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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Canada

ISSN: 1925-0630 (print)
1925-0649 (online)

Catalogue number: H113-5/2017-7E (print version)
H113-5/2017-7E-PDF (PDF version)

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Background

In Canada, tebufenozide is under re-evaluation by Health Canada's Pest Management Regulatory Agency (PMRA). The PMRA re-evaluates registered pesticides to determine whether the use of these products continues to be acceptable in terms of value, human health and the environment according to current standards.

Tebufenozide is an insecticide registered for control of larval Lepidoptera (in other words, butterflies and moths). It is registered for use on terrestrial and greenhouse food crops, greenhouse and outdoor ornamentals, and for forest and woodlots management. As of 7 January 2017, there are one technical grade product and two end-use products registered for use in Canada.

Under the authority of section 16 of the *Pest Control Products Act*, the registrant of tebufenozide was notified of the initiation of the re-evaluation of tebufenozide. Following this, the registrant of tebufenozide technical grade active ingredient in Canada indicated its support of all uses included on the labels of end use products in Canada.

The re-evaluation project plan below outlines the timeline, the anticipated areas of focus for the risk assessments, and the data requirements for the re-evaluation of tebufenozide.

Re-evaluation Project Plan

Anticipated Re-evaluation Timeline

The re-evaluation of tebufenozide is defined as a Category 1 as described in DIR2016-04, *Management of Pesticides Re-evaluation Policy*, which was adopted on 1 December 2016. However, because this re-evaluation was initiated prior to the publication of DIR2016-04, the proposed re-evaluation decision for tebufenozide is anticipated to be published for consultation by February 2019. The re-evaluation timeline may be updated if, during the risk assessment, the PMRA identifies additional areas of focus that should be considered.

Human Health Risk Assessment

New assessments will be conducted for toxicology and dietary exposure. Existing assessments with minor updates are considered to be adequate to support the re-evaluation of tebufenozide for the other aspects of human health assessment.

Environmental Risk Assessment

New assessments will be conducted for environmental fate, water modelling and exposure.

Value

The value of tebufenozide will be considered. The viability of alternatives will be examined for certain uses if risks of concern requiring mitigation are identified.

Data Requirements

The PMRA has identified the need for the technical registrant to provide data for tebufenozide related to toxicology and environment. Relevant data/studies have been requested from the technical registrant. A summary of the data call-in is found in the PMRA's Public Registry, found online at http://www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#ppid. For a list of data categories that have been required, see Appendix I. In addition, information regarding the registered use pattern has been requested from the registrants, to inform the risk assessments.

Additional Information

PMRA documents can be found in the Pesticides and Pest Management section of Health Canada's website at healthcanada.gc.ca/pmra. PMRA documents are also available through the Pest Management Information Service:

Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply)
Fax: 613-736-3798
E-mail: pmra.infoserv@hc-sc.gc.ca

Appendix I Data Requirements Under Subsection 19(1) of the *Pest Control Products Act* for the Re-evaluation of Tebufenozide

Toxicology

DACO 4.2.9	Acute toxicity
DACO 4.5.5	Genotoxicity: In vitro mammalian cell assay
DACO 4.5.7	Genotoxicity: In vivo cytogenetics
DACO 4.6.3	Acute studies: Acute inhalation - EP
DACO 4.8	Other toxicology studies
DACO 12.5.4	Foreign reviews of toxicity (if available)

Environment

DACO 8.2.2.2	Analytical methods: Sediment
DACO 8.2.2.3	Analytical methods: Water
DACO 8.2.2.4	Analytical methods: Biota
DACO 8.2.3.4.2	Biotransformation in soil: Aerobic soil 20-30°C
DACO 9.2.4.3	Hive study (including brood)
DACO 9.2.4.4	Non-target terrestrial invertebrates: Honey bee
DACO 9.3.2	Non-target freshwater invertebrates (*Daphnia* sp. Acute)
DACO 9.3.3	Non-target freshwater invertebrates (*Daphnia* sp. Chronic)
DACO 9.4.5	Non-target marine invertebrates: chronic (mollusk or crustacean)
DACO 9.5.2.1	Acute studies: cold water fish (rainbow trout)
DACO 9.5.3.1	Sublethal and chronic studies: fish, early life cycle toxicity test
DACO 9.5.3.2	Sublethal and chronic studies: fish, life cycle toxicity
DACO 9.8.4	Non-target plants: terrestrial vascular plants
DACO 9.8.5	Non-target plants: aquatic vascular plants